K071606

510(k) Summary

AUG 31 2007

1. General Information

Trade Name of Device: "BioSign™ Central Station"

Common/Usual Name: Accessory to multi-parameter patient monitor (bedside or ambulatory)

Classification Name: Physiological Patient Monitor (without arrhythmia detection or alarms)

Submitters Name and Address:

OBS Medical
Hamilton Crossing 4
12900 N. Meridian St
Carmel, IN 46032
Tel 317-581-9236
Fax 317-581-8941

Manufacturer:

Oxford BioSignals Limited
Brook House
174 Milton Park
Abingdon
Oxon OX14 4SE
United Kingdom

2. Device Description

BioSign™ Central Station is a software accessory to standard multiple parameter physiological patient monitors (bedside or ambulatory) or clinical information systems. It operates on a standard PC, or personal computer.

BioSign™ is a software device that through advanced signal processing can combine physiological signals in order to produce a single index (BioSign index) representation of patient condition.

BioSign™ is a computerized analysis system that can accept multiple channels of physiological data (for example heart rate, respiratory rate, temperature, blood pressure and oxygen saturation as inputs). Through advanced signal processing, BioSign can identify changes in patient status.

3. Indications for Use

The BioSign™ Central Station is an accessory to multi-parameter patient monitors (bedside or ambulatory) or clinical information system and is indicated for use by health care professionals with those non-pediatric high dependency care patients for whom multi-parameter patient monitoring has been routine.

The BioSign™ Central Station provides the clinician with a status index (BioSign™ Index) based on a weighted average of five vital signs namely heart rate, respiration rate, temperature, oxygen saturation and blood pressure. The BioSign™ index is a single measure of a patient's condition and represents how different the patient's vital signs are with respect to normality. BioSign™ is an adjunct to and is not intended to replace vital signs monitoring.

The BioSign™ Central Station displays BioSign indices for multiple patients.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

4. Substantial Equivalence

The BioSign™ Central Station device is substantially equivalent to the following devices:

Predicate device: BioSign™
Company: OBS Medical
510(K) Number: K053112

The BioSign™ Central Station is a software accessory to multi-parameter physiological patient monitors and as such is substantially equivalent to the BioSign™ bedside monitor.

BioSign™ Central Station is substantially equivalent to BioSign in that its displayed graphical representation of the fused vital signs is created by computer analysis and provides decision support to a clinician in the determination of normality based on a model derived from historic clinical data. Both devices are adjuncts to vital sign monitoring. Both devices use the same algorithm to fuse the vital signs and display the BioSign index.

Please note BioSign™ Central Station, does not include any alarms or parameter thresholds. BioSign is an adjunct to and is not intended to replace vital sign monitoring

5. Performance Studies

Design verification: Design verification testing of the BioSign™ Central Station hardware and software against the specified requirements has been conducted and the BioSign™ device has been found to meet the specifications.

Design validation: Design validation testing of the BioSign™ index model has been conducted and concluded that device specifications conformed with user needs and intended use.

Electrical Safety: The BioSign™ Central Station is composed of standard, off the shelf PC computer components. There is no contact with the patient and the user assumes no risk greater than that when using a standard desk-top personal computer.

6. Conclusion

Based upon the indications for use and performance studies the BioSign™ Central Station has been shown to be substantially equivalent for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2007

OBS Medical
c/o Mr. Wayne Nethercutt
Director, Regulatory and Clinical Affairs
1290 N. Meridian
Carmel, IN 46032

Re: K071606
BioSign™ Central Station
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: August 13, 2007
Received: August 17, 2007

Dear Mr. Nethercutt:

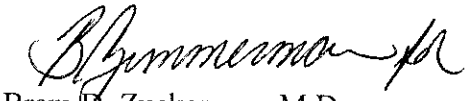
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071606

INDICATIONS FOR USE

510(k) Number K071606

Device Name: **BioSign™** Central Station

Indications For Use:

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The BioSign™ Central Station provides the clinician with a patient status index (BioSign™ Index) based on a weighted average of five vital signs namely heart rate, respiration rate, temperature, oxygen saturation and blood pressure. The BioSign™ index is a single measure of the patient's condition and represents how different the patient's vital signs are with respect to normality. BioSign™ is an adjunct to and is not intended to replace vital signs monitoring.

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Prescription Use __X_____ AND/OR Over-The-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071606